Modified PTO/SR/33 (10-05)

			Docket Number		
PRE-APPEAL BRIEF REQUEST FOR REVIEW		IEW	w		
			Q90825		
		Application	Number	Filed	
Mail Stop AF Commissioner for Patents		10/552,685		October 11, 2005	
		First Named Inventor			
P.O. Box 1450 Alexandria,	VA 22313-1450	Yukako FUKUHIRA			
		Art Unit		Examiner	
		1615		Caralynne E. Helm	
	WASHINGTON OFFICE				
	23373				
	COSTONIER NOMBUR				
Applicant requests review of	of the final rejection in the	above-ident	ified applica	tion. No	
amendments are being filed			**		
This request is being filed v	with a notice of appeal				
The review is requested for Note: No more than i	the reasons(s) stated on the five (5) pages may be prove		heet(s).		
☑ I am an attorney or agent	t of record.				
Registration number 33,725			Bush		
-			Signature		
			Bruce E. Kramer		
			Typed or printed name		
			(202) 293-7060		
		Telephone number			
			<b>A</b>	+2 2010	
-			August 2, 2010		

#### PATENT APPLICATION

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Docket No: Q90825

Yukako FUKUHIRA, et al.

Appln. No.: 10/552,685 Group Art Unit: 1615

Confirmation No.: 3807 Examiner: Caralynne E. Helm

Filed: October 11, 2005

For: BIODEGRADABLE FILM HAVING HONEYCOMB STRUCTURE

### PRE-APPEAL BRIEF REQUEST FOR REVIEW

### MAIL STOP AF - PATENTS

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to the Pre-Appeal Brief Conference Pilot Program, and further to the Examiner's Final Office Action dated February 7, 2010, Applicant files this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal.

The present claims are rejected as obvious over (1) Shimomura in view of Johnsson, Nishikawa, and Maruyama, and (2) Shimomura in view of Huang, Nishikawa, and Maruyama.

In response, Applicants note initially that the Examiner relies on Johnsson and Huang for establishing the fact that phosphatidyl ethanolamine dioleoyl (DOPE) forms an inverted hexagonal structure in aqueous solution. However, this fact cannot be applied for producing honeycomb-structure film of the present invention for the following reasons.

 i) According to the present invention, the honeycomb structure can only be formed using hydrophobic organic solvent such as chloroform, as discussed further below. The finding mentioned by the Examiner is in an aqueous solution, and it cannot be expanded to circumstances in a hydrophobic organic solution, since inter-molecular assembly of DOPE is expected to be completely different depending on the circumstances.

ii) According to the present invention, DOPE is added to a polymer solution for producing the honeycomb structure, as discussed further below. This means that the circumstance of DOPE is quite different from the pure form as described in the cited reference.

Despite these arguments, in the final Office Action the Examiner maintained the position that the present invention is obvious by providing two lines of reasoning to show that the present invention is an obvious variant over Shimomura. The key point of the two lines of reasoning lies in the fact that phospholipids form an inverted hexagonal structure in aqueous solution, citing Johnsson et al. and Huang. On that basis, according to the Examiner, the inverted hexagonal structure of the prior art can be equated to the honeycomb structure of the present invention. However, this is not the case, and thus the Examiner's logic cannot be maintained, as follows.

# A. "Inverted hexagonal phase" of the prior art

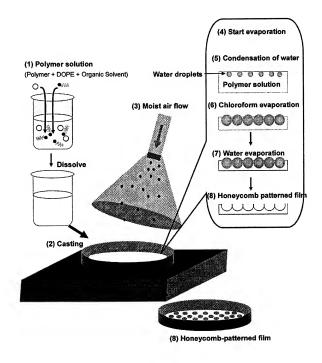
Phosphatidylethanolamine may form an inverted hexagonal structure in aqueous solution pursuing the most stable form under a given condition. In the "inverted hexagonal phase" of phosphatidylethanolamine, the internal portion is the hydrophilic region and external portion is the hydrophobic region of a phosphatidylethanolamine molecule, and a tubular structure is formed (see Fig. 1 on page 3 of the Response filed June 2, 2010 and the associated discussion).

In contrast, in a hydrophobic organic solvent, phosphatidylethanolamine can be dissolved, and the molecules are dispersed and do not form an inverted hexagonal structure (see Fig. 2 on page 3 of the Response filed June 2, 2010 and the associated discussion).

## B. Honeycomb structure of the present invention

Applicants would now like to explain the mechanism of forming a honeycomb structure of the present invention in detail using the figure below.

- A polymer and an amphiphilic molecule are dissolved in an organic solvent such as chloroform.
  - (2) The polymer solution is cast onto a plane surface.
  - (3) On the surface of the polymer solution, moisturized airflow is provided.
- (4) The volatile organic solvent used evaporates gradually from the surface and the temperature of the surface decreases owing to evaporative latent heat.
- (5) A portion of the moisture in the airflow condenses and forms water droplets on the chilled surface. These droplets continue to grow and sink into the polymer solution.
- (6) Since the water droplets are covered with amphiphilic molecules, wherein the hydrophobic portion of the molecules are oriented outside of the droplets, the surface of the droplets is hydrophobic and this prevents fusion of the droplets and stabilizes them. The organic solvent in the polymer solution continues to evaporate.
- (7) After complete evaporation of the organic solvent, water of the droplets evaporates at the end as well.
  - (8) A honeycomb structure of the polymer remains.



Schematic illustration of honeycomb-patterned film formation.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

U.S. Application No. 10/552,685

Attorney Docket No. Q90825

Thus, the honeycomb structure of the present invention is an imprint of uniformly packed

water droplets. In contrast, the inverted hexagonal phase of the prior art is a bundle of tubular

structures.

In addition, as a consequence of the mechanism of forming the honeycomb structure of

the present invention, dissolving amphiphilic molecules in a volatile hydrophobic organic solvent

together with the polymer is necessary. Therefore, even if the teaching of an aqueous solution in

the prior art were applied to Shimomura, an ordinary artisan could not have reached the present

invention.

While the Examiner indicates in the Advisory Action that the instant claims are not

drawn to a method of making a film, it is submitted that the above method-related discussion

explains what is necessary to form the presently claimed film, and why the prior art does not

result in the presently claimed film.

Thus, Applicants submit that the present invention is not obvious over the cited art

combinations, and withdrawal of these rejections is respectfully requested.

Respectfully submitted,

Registration No. 33,725

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

> 23373 CUSTOMED NUMBER

Date: August 2, 2010

5